ELECTRON
R&D and Manufacturing Company

NIPK Electron Co
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www.electronxray.com e-mail secretary@electronxray.com

K122589

Section 3: 510(k) Summary

OCT 5 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

Date Summary Prepared: August 20, 2012

1. **Submitter's Identification:**

Applicant:

NIPK Electron Co
Leningradskaya ul. bldg.52a, lit.A,
Pos. Pesochny, Saint-Petersburg, 197758,
Russia
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Contact – Julia Nikitina

Submitter:

mdi Consultants, Inc.
55 Northern Blvd
Great Neck, NY 11021
Telephone: 516-482-9001
Fax: 516-482-0186
Contact: Jigar Shah, MS, RAC

2. **Name of Device:**

Device trade name: DFP4343C7
Common name: Digital X-ray Detector
Classification: Solid State X-ray Imager (Flat Panel/Digital Imager)
Class II
MQB
21 CFR 892.1650

3. **Predicate Device Information:**

Manufacturer: Samsung Mobile Display Co., Ltd.

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Trade/proprietary name: LTX240AA01-A
Common Name: Digital Flat Panel X-Ray Detector
510(k) Number: K090742

4. Device Description:

4.1 General

Digital X-ray Detector DFP4343C7 is a medical image processing unit. Especially, advanced digital imaging process allows considerably efficient diagnosis, all kind of information management, real-time sharing of image information on network.
DFP4343C7 is a high-resolution digital imaging detector designed for general radiography. It is intended to replace conventional film radiography technique .
DFP4343C7 consists of Electro X-ray Unit, Software package(S/P), Power Supply Unit and cables set.

4.2 Features

DFP 4343C7 is an X-Ray image acquisition device that is based on flat-panel. This device should be integrated with an operating PC and an X-Ray generator. It can do to utilize as digitalizing X-ray images and transfer for radiography diagnostic.

5. Indication for Use:

The Digital X-ray Detector DFP4343C7 is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

6. Substantial Equivalence:

NIPK Electron Co believes that Digital X-ray Detector DFP4343C7 is substantially equivalent to LTX240AA01-A Digital Flat Panel X-Ray Detector of Samsung Mobile Display Co., Ltd.

7. Discussion of Non-Clinical Tests Performed for Determination of

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Substantial Equivalence are as follows:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed and EMC testing was conducted in accordance with standard IEC-60601-1-2.

Biocompatibility testing was conducted in accordance with Standard ISO 10993-1.

Safety of Programmable medical systems in accordance with IEC 60601-1-4 was performed.

A product risk management is executed according to ISO 14971 and all risks are reduced to an acceptable level by implementation and verification of appropriate measures.

Non-clinical considerations according to FDA "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" was performed. All test results were satisfactory.

7. Discussion of Clinical Tests Performed:

Clinical considerations according to FDA "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" was performed. All test results were satisfactory.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification NIPK Electron Co concludes that the Digital X-ray Detector DFP4343C7 is substantially equivalent to the predicate in intended use, operation, safety, function, and is safe and effective for its' intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 5 2012

NIPK Electron Co.
% Mr. Jigar Shah, M.S., RAC
Official Correspondent
mdi Consultants, Inc.
55 Northern Boulevard, Suite 200
GREAT NECK NY 11021

Re: K122589
Trade/Device Name: Digital X-ray Detector DFP4343C7
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: August 20, 2012
Received: August 24, 2012

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

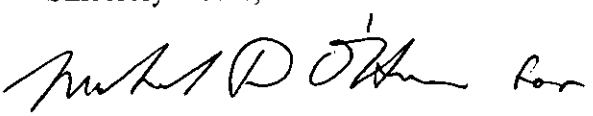
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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Section 2: Indications for Use

510(k) Number (if known): K122589

Device Name: Digital X-ray Detector DFP4343C7

Indications For Use:

The Digital X-ray Detector DFP4343C7 is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

Prescription Use X **(Per 21 CFR 801 Subpart D)** OR **Over-The Counter Use** _____ **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122589